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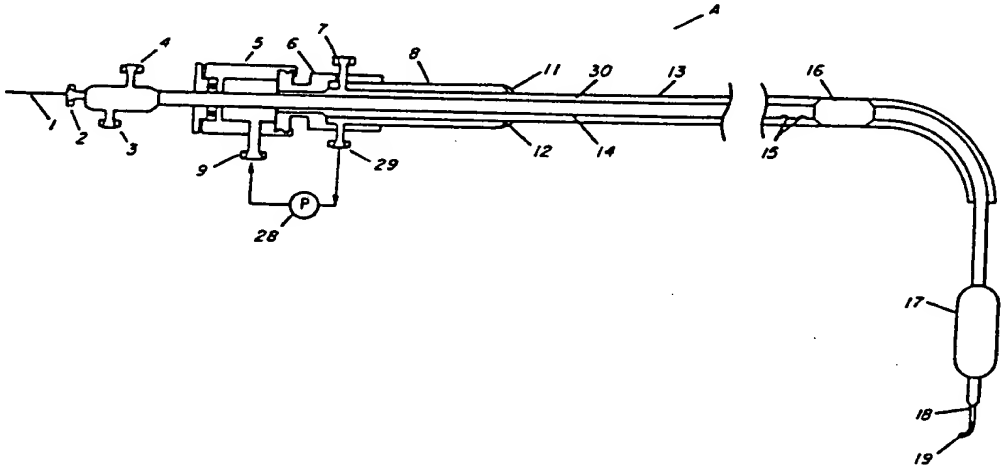
(54) Title: PERFUSION CATHETER



(57) Abstract

A low-profile angioplasty catheter (14) is disclosed which is insertable through a guiding catheter (13). The angioplasty catheter has two balloons. The distal balloon (17) dilates the stenosis. The proximal balloon (16) is separately inflatable and selectively closes the annular passage (30) between the angioplasty catheter and the guiding catheter. The angioplasty catheter has a central lumen with a series of openings allowing fluid communication from the central lumen into the annular passage proximally of the balloon which seals the annular passage. While the first balloon (17) is inflated to dilate the stenosis, blood can be withdrawn from an arterial source through a lumen (11, 12) (or plurality thereof) in the guiding catheter and pumped into the annular passage (30) between the angioplasty catheter and the guiding catheter. The blood then passes through the openings (15) proximal to the proximal balloon (16) into the central lumen of the PTCA catheter and flows beyond the distal tip (18) of the angioplasty catheter to maintain circulation of the patient's blood at a point distal of the stenosis.

TITLE: PERFUSION CATHETER

FIELD OF THE INVENTION

The field of the invention relates to perfusion catheters, specifically those adapted to perform angioplasty procedures.

BACKGROUND OF THE INVENTION

Performing coronary angioplasty requires inflation of a balloon in an arterial passage in an effort to clear a flowpath for blood by expanding the stenosis. When the balloon is deflated, the result is an increase in the available cross-sectional area for blood flow in the arterial passage. The problem with the angioplasty procedure is that during balloon inflation, the circulation is cut off. This can result in ischemia and electrocadiologic changes. Other observed phenomena occurring during or shortly after coronary angioplasty are abrupt reclosure where the stenosis after the conclusion of coronary angioplasty realigns itself so as to reclose the arterial passage. Alternatively, portions of the stenosis can break loose at one end and obstruct the flowpath. This is known as intimal flaps. Obviously, all of these conditions result in emergencies, with potential for severe consequences if not immediately addressed.

One method that has been used to reduce the onset of ischemia, electrocardiologic and ST segment changes has been to perfuse blood through a lumen of the angioplasty catheter during balloon inflation. The perfusion of blood can be successful in eliminating ischemia and ST segment changes in the arterial flowpath distally of the inflated balloon and to protect the involved myocardium. With perfusion, only the

portion of the intima in contact with the balloon during inflation, and any side branches involved therein, can be the source of an ischemic reaction.

It has also been learned that it is advantageous to keep the profile of the catheter as small as possible to allow it to be advanced to the site of the stenosis. At the same time, while a low profile is desirable, the angioplasty catheter needs to have sufficient column strength so as to have good pushability and torquability reactions to allow advancement of the catheter to the stenosis.

To accomplish perfusion of blood during inflation of the balloon, various blood pumps have been developed in the past. Most of these pumps have put out fairly low pressures up to 60 psi of mercury. Primarily these have been diaphragm- and roller-type pumps.

The advent of very low-profile catheters having central lumen inside diameters in the order of 0.020 inch at the distal region has meant that higher and higher pressures were needed to be developed by such pumps in order to pump the expected volume of about 60 cc/min. Even in some catheters which had a central lumen of approximately 0.032 inch for substantially their entire length of about 130-140 cm., with a taper of the central lumen down to approximately 0.020 inch, pressures in the order of 125-200 psi were required to be able to perfuse the required volume of approximately 60 cc/min. Typical of such catheters involving a taper at the distal end is U.S. Patent 4,921,483, invented by these Applicants.

Pumping blood up to high pressures was the downside effect of causing hemolysis.

It is desirable to develop ways to perfuse the required volume of blood without having to raise the pressure of the blood to such levels while at the same time being able to use a low-profile catheter.

Of special interest in the prior art are U.S. Patents 4,790,315 and 4,661,094, assigned to ACS Corporation of Mountain View, California. These patents illustrate catheters which have perforations throughout their length into a central lumen. These catheters perfuse by virtue of using the patient's blood pressure proximally of the stenosis. The patient's blood pressure proximally of the stenosis drives the blood through the openings and out the distal end of the catheter. One serious disadvantage of the use of such catheters for perfusion is that at the time the patient requires angioplasty, the patient has fairly low blood pressure or is in AV block, and the patient's ventricular ejection fraction is low. These elements comprise the driving force to push the blood through the openings illustrated in U.S. Patents 4,790,315 and 4,661,094. Another shortcoming of the catheter illustrated in the '315 patent is that it has a relatively high profile, to the extent that it cannot be used as a primary catheter. Instead, a more slender catheter must be inserted into the stenosis to widen it initially before the catheter of the '315 patent can be used. While the catheter of the '094 patent displays a method of perfusion, it is not a balloon catheter. Instead, the catheter in the '094 patent must be carefully pushed through a stenosis to allow perfusion beyond it. In both of these patents, the requisite flowrate is difficult to achieve with the available pressure, which is only in the range of about 4 psi with the best of conditions. Since there is such a low motive pressure available using the patient's own blood pressure, numerous holes need to be provided for access to the central lumen without a significant pressure drop. The use of numerous openings into the central lumen can also affect the column strength and, hence, pushability of the catheters therein disclosed.

SUMMARY OF THE INVENTION

A low-profile angioplasty catheter is disclosed which is insertable through a guiding catheter. The angioplasty catheter has two balloons. The distal balloon dilates the stenosis. The proximal balloon is separately inflatable and selectively closes the annular passage between the angioplasty catheter and the guiding catheter. The angioplasty catheter has a central lumen with a series of openings allowing fluid communication from the central lumen into the annular passage proximally of the balloon which seals the annular passage. While the first balloon is inflated to dilate the stenosis, blood can be withdrawn from an arterial source through a lumen (or plurality thereof) in the guiding catheter and pumped into the annular passage between the angioplasty catheter and the guiding catheter. The blood then passes through the openings proximal to the proximal balloon into the central lumen of the PTCA catheter and flows beyond the distal tip of the angioplasty catheter to maintain circulation of the patient's blood at a point distal of the stenosis.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a sectional view of the catheter assembly of the present invention, illustrating the balloons in an inflated position.

Figure 2 is a sectional view adjacent the proximal end of the guiding catheter assembly of the present invention.

Figure 3 is a sectional view of the angioplasty catheter proximally of both balloons illustrated in Figure 1.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The apparatus A is illustrated in Figure 1. A guiding catheter 13 has an outer sheath 8 integral to the guiding catheter connected adjacent its proximal end. The guiding

catheter 13 terminates in a hub 6. As shown in Figure 2, sheath 8 has a plurality of lumens 20, 21 and 22. Lumen 20 can be used to monitor pressure in the patient's artery (not shown). Lumen 20 terminates in an open end 11 where the patient's blood pressure can be sensed in view of fluid communication from end 11 through lumen 20 to connection 7. A suitable pressure transducer can be connected to connection 7 to provide continuous monitoring of the patient's blood pressure during inflation of balloon 17. Additional lumens 21 and 22 are provided for the purposes of blood aspiration. The patient's blood in the artery proximally to the inflated distal balloon 17 is drawn through open ends 12 through lumens 21 and 22 into connection 29, which extends from the guiding catheter hub 6. Connection 29 is the suction connection for pump 28. The discharge of pump 28 is attached to connection 9, which is a side port to the hemostasis connection 5. Alternatively, guiding catheter hub 6 and hemostasis connector 5 can be made integral.

As shown in Figure 1, the PTCA catheter 14 extends through guiding catheter 13, forming an annular passage 30 between PTCA catheter 14 and guiding catheter 13. A plurality of openings 15 provide fluid communication between lumen 26 (see Figure 3) and annular passage 30. Pump 28 discharges into connection 9, which is in fluid communication with annular passage 30, which in turn is in fluid communication with lumen 26 through openings 15. A proximal balloon 16 can be selectively inflated to seal off annular passage 30. Proximal balloon 16 is inflated via proximal balloon inflation lumen 24, which extends from proximal balloon 16 to the proximal end of the catheter at connection 3. Suitable media can be injected into connection 3 to selectively inflate or deflate balloon 16. Similarly, the distal balloon 17 is in fluid communication with distal balloon inflation lumen 25, which

extends substantially the length of the catheter to connection 4. The distal balloon 17 can be selectively inflated or deflated by injecting or withdrawing appropriate media into or from connection 4. The proximal end of the PTCA catheter 14 has a guidewire port 2, having a centerline substantially coincident with the longitudinal axis of the PTCA catheter 14 to allow a guidewire 1 to pass completely through lumen 26 and out the PTCA distal opening 18, wherein the tip 19 of guidewire 1 is shown to extend. To enhance the column strength and pushability of the PTCA catheter 14, a tube 27 can be optionally installed within lumen 26. The guidewire 1 can pass through the inside of tube 27. Preferably, tube 27 extends the length of PTCA catheter 14 to a point proximally of openings 15. Instead of a tube 27, a stiffness rod can be employed and preferably located in lumens 24 or 25.

Typically, the center of proximal balloon 16 is about 15-25 cm from the center of the distal balloon 17. The overall length of the PTCA catheter 14 is in the order of 130-140 cm.

In use, the guiding catheter 13 is advanced from the femoral artery up to the aortic root over a standard 0.032-0.035-inch guidewire and is placed in the appropriate coronary artery. Thereafter, the PTCA catheter 14 is advanced over guidewire 1 through the guiding catheter 13 until the distal balloon 17 is located in the stenosis. Thereafter, balloon 17 is inflated. When distal hemoperfusion is desired, balloon 16 is inflated to seal off the channel 30. The annular passage 30 is then effectively closed off. The arterial passage proximal to the inflated balloon 17 is in fluid communication with ends 12 of lumens 21 and 22. Pump 28 is activated to pump the patient's blood from the artery proximally to the inflated balloon 17, back into connection 9, through the annular passage 30, through openings 15, back into the lumen 26 of PTCA catheter 14, through the distal opening 18 of PTCA

catheter 14, distally of balloon 17. It should be noted that prior to pumping of the blood, saline is pumped into the proximal end of the catheter through lumen 26 and is retained within lumen 26 during the blood pumping to prevent the blood passing through openings 15 from traveling toward the proximal end of the catheter. In other words, the proximal length of lumen 26 up until openings 15 is initially filled with saline and the proximal end of said lumen 26 is closed off. Thus, when the blood is pumped through openings 15, it cannot move in the proximal direction but moves distally out the distal end of the catheter 14 at point 18. One immediately apparent advantage to this scheme is that the patient's blood pressure can be continuously monitored because it is continuously sensed through opening 11, which is in fluid communication with connection 7, to which a pressure transducer (not shown) is connected. Additionally, the available cross-sectional area for substantially the entire length of the catheter 14 is dramatically increased by pumping the blood on the outside of catheter 14, rather than through central lumen 26. Typical guiding catheters have inside diameters of 0.080 inch, while the PTCA catheter described herein has outside diameters of 0.045 inch. The resulting cross-sectional area of annular passage 30 is approximately 0.01375 sq.in. which is considerably larger than the best possible area available in the typical PTCA catheter for distal hemoperfusion, which is approximately 0.032 inches in diameter, with a resulting area of approximately 0.0008 sq.in. Thus, the flow cross-sectional area for substantially the entire length of a PTCA catheter 14 which is normally about 130-140 cm. is about 17 times greater than trying to perfuse the blood through the lumen 26 of the PTCA catheter 14 over its entire length. As a result, the possibility of onset of hemolysis is reduced. The increase in the available cross-sectional area for perfusing blood results

in lower pressures required at the pump 28 since only approximately 15-25 cm. of the flowpath is through the central lumen 26, which has a smaller diameter of approximately 0.020 inch. The designs of the pumps implied can be more economical, and battery powered pumps can be used over longer periods of time due to the decrease in discharge pressures that need to be developed. Another advantage of the catheter assembly as disclosed in the present invention is that the guidewire can remain in position within lumen 26 during the perfusion process. In prior designs where the blood must be perfused through lumen 26, the presence of the guidewire offered significant resistance to blood flow, thereby increasing the necessary pressures having to be developed by pump 28. Accordingly, in response to this problem, surgeons have pulled back the guidewire or even pulled it out to reduce the resistance to flow during perfusion. It has always been important to leave the guidewire in position because it facilitates advancing the catheter or repositioning the catheter in the appropriate location. It should be noted that it is within the spirit of the invention to provide a separate lumen for the guidewire 1 and for perfusion. Another advantage of the apparatus A of the present invention is that the guiding catheter 13 is built with sheath 8 to allow the pressure measurement through opening 11 and the blood aspirated through opening 12 without having to install additional catheters in the patient to provide for these needs. This results in decrease in trauma to the patient due to the compact design of the apparatus of the present invention. Those skilled in the art will appreciate that alternatively through tube 27, a stiffening wire can be employed without departing from the spirit of the invention. When used in this application, stiffener tube 27 also encompasses a stiffening rod. A blood pump, such as illustrated in co-pending application Serial No. 07/347,406, also

invented by these Applicants, can be employed as pump 28 illustrated in Figure 1. This is a piston-type pump with a pulsation dampener and is designed not to have any dead spots therein. However, the pressures that this pump can develop, *i.e.*, in the order of 200 psi, will not necessarily be required in view of the dramatic increase in the flowing cross-sectional area of the apparatus A of the present invention. Since the flowing cross-sectional area proximally to openings 15 has been increased in the order of approximately 17-20 times, the available cross-sectional area of prior low-profile designs, pump pressures in the order of 50-100 psi will be sufficient to deliver approximately 60 cc/min. distally of balloon 17 through opening 18.

Catheters of the type disclosed by these inventors in U.S. Patent 4,921,483 can be employed with the apparatus A of the present invention. The description and specification as disclosed in such patent is incorporated by reference herein as if fully set forth, as is this Applicant's disclosure in U.S. Application Serial No. 07/347,406 entitled "Blood Pump." Applicant also incorporates in this application as if fully set forth its disclosures in U.S. Patent 4,884,573, entitled "Very Low Profile Angioplasty Balloon Catheter with Capacity to Use Steerable, Removable Guidewire," co-pending U.S. Application Serial No. 442,157, entitled "Low Profile Catheter," and U.S. Patent 4,921,483 and the applications leading thereto, specifically U.S. Application Serial No. 811,162, filed December 19, 1985.

The foregoing disclosure and description of the invention are illustrative and explanatory thereof, and various changes in the size, shape and materials, as well as in the details of the illustrated construction, may be made without departing from the spirit of the invention.

AMENDED CLAIMS

[received by the International Bureau on 4 November 1992 (04.11.92); claims 1-15 and 17-25 amended; claim 16 unchanged (8 pages)]

1. An apparatus for perfusing blood beyond a blockage created in a patient's blood vessel during catheterization, comprising:

an elongated catheter having a proximal end and a distal end;

at least one first lumen extending through the distal end of said catheter;

guide means for guiding said catheter in said vessel, said guide means surrounding at least a portion of said catheter creating an annular passage therebetween;

valve means on said catheter between said proximal and distal ends for selectively closing said annular passage;

said lumen having flow communication with said annular passage at a point proximal to said valve means;

perfusion means in fluid communication with said vessel proximally of said valve means and in fluid communication with said annular passage proximally of said valve means for withdrawing blood from a blood vessel in which said catheter and guide means are disposed and pumping it through said annular passageway;

whereby, upon selective operation of said valve means blood can be perfused from the outside of said catheter through said annular passage and into said lumen through said flow communication therebetween and out of said catheter beyond a blockage in the patient's circulatory system.

2. The apparatus of claim 1, wherein said catheter further comprises:

means for selectively expanding within in a blood vessel in which said catheter is disposed to clear a blockage therein;

said expanding means being disposed distally of said guide means and on said catheter; and

means for actuating said expanding means from the proximal end of said catheter.

3. The apparatus of claim 2, wherein:

said valve means is mounted to said catheter proximally of said expanding means; and further comprising

means operatively connected to said valve means from said proximal end of said catheter for selectively energizing said valve means from such proximal end.

4. The apparatus of claim 3, wherein:

said guide means is coaxial with said catheter and extends from said proximal end of said catheter, over said valve means and terminates proximally of said expanding means.

5. The apparatus of claim 4, wherein:

said actuating means for said expanding means is a second lumen in said catheter, extending from adjacent its proximal end to said expanding means; and

said energizing means is a third lumen in said catheter, extending from adjacent its proximal end to said valve means.

6. The apparatus of claim 5, wherein:

said first lumen is larger in cross-sectional area than said second or third lumens.

7. The apparatus of claim 5 wherein said expanding and valve means are balloons selectively inflatable independently of each other through said second and third lumens respectively; and

said guide means is a guiding catheter.

8. The apparatus of claim 7, further comprising:

sheath means on to said guide means to allow flow access therebetween from a blood vessel in which said catheter and guide means are disposed.

9. The apparatus of claim 8, wherein said sheath means further comprises:

at least one first channel between said sheath means and said guide means extending substantially parallel to said guide means for a portion of the length of said guide means to allow withdrawal of blood from said blood vessel;

said perfusion means including pump means in fluid communication with said first channel and said annular passage for pumping the patient's blood through said passage and into said lumen of said catheter.

10. The apparatus of claim 9, further comprising:

at least one second channel on said sheath means in fluid communication with said blood vessel and the proximal end of said catheter and said guide means adapted at said proximal end for fluid communication to pressure-measuring means to allow continuous measurement of pressure in said blood vessel.

11. The apparatus of claim 1, in which said perfusion means includes:

sheath means on said guide means to allow flow access therebetween from a blood vessel in which said catheter and guide means are disposed.

12. The apparatus of claim 11, further comprising:

at least one first channel between said sheath means and said guide means extending substantially parallel to said guide means for a portion of the length of said guide means to allow withdrawal of blood from said blood vessel;

said perfusion means including pump means in fluid communication with said first channel and said annular passage for pumping the patient's blood through said passage and into said lumen of said catheter.

13. The apparatus of claim 12, further comprising:

at least one second channel on said sheath means in fluid communication with said blood vessel and the proximal end of said catheter and said guide means adapted at said proximal end for fluid communication to pressure-measuring means to allow continuous measurement of pressure in said blood vessel.

14. The apparatus of claim 13, wherein said catheter further comprises:

means for selectively expanding within a blood vessel in which said catheter is disposed to clear a blockage therein;

said expanding means being disposed distally of said guide means and on said catheter; and

means for actuating said expanding means from the proximal end of said catheter.

15. The apparatus of claim 14, wherein:

said valve means is mounted to said catheter proximally of said expanding means; and further comprising

means operatively connected to said valve means from said proximal end of said catheter for selectively energizing said valve means from such proximal end.

16. The apparatus of claim 15, wherein:

said guide means is coaxial with said catheter and extends from said proximal end of said catheter, over said valve means and terminates proximally of said expanding means.

17. The apparatus of claim 16, wherein:

said actuating means for said expanding means is a second lumen in said catheter, extending from adjacent its proximal end to said expanding means; and

said energizing means is a third lumen in said catheter, extending from adjacent its proximal end to said valve means.

18. The apparatus of claim 17, wherein:

said first lumen is larger in cross-sectional area than said second or third lumens; and further comprising

stiffener means disposed in said second or third lumen to stiffen the proximal portion of said catheter; and

a removable guidewire selectively extendable through and beyond said first lumen and disposed within said tube.

19. The apparatus of claim 17 wherein said expanding and valve means are balloons selectively inflatable independently of each other through said second and third lumens respectively; and

said guide means is a guiding catheter.

20. The apparatus of claim 1, wherein:

said annular passage has a cross-sectional area at least 10 times greater than said first lumen; and said perfusion means includes

pump means in fluid communication with said annular passageway to pump blood at least 60 cc/min. out the distal end of said lumen when said catheter is about 140 cm long with a developed pressure at said pump means not exceeding 100 psig.

21. The apparatus of claim 1, wherein said elongated catheter further comprises:

an elongated body having a proximal and distal segment, said body defining said first lumen extending therethrough;

an elongated tip segment connected adjacent to the distal end of said distal segment of said body, said tip defining at least one substantially smooth bore lumen therethrough, said first lumen in said body in flow communication with said smooth-bore lumen in said tip, thereby allowing the catheter to be advanced over a guide extending through said lumen in said body in said tip;

said body being made of a harder material than the material of said tip;

a balloon mounted in close proximity to the outer surface of said distal segment of said body defining a balloon cavity therebetween, said balloon having a proximal and distal neck, said balloon disposed substantially proximally to said tip, juncture means for providing a transition between said tip and said distal segment of said body, said distal neck of said balloon mounted adjacent to the juncture between said elongated tip segment and said distal end of said distal segment of said body;

said proximal neck of said balloon mounted to said elongated body;

said distal segment of said body being substantially nondistensible as the balloon is inflated to substantially its full normal operating inflation pressure; and

means within said body for selectively inflating and deflating said balloon through said cavity.

22. A method of perfusing blood during balloon angioplasty, comprising:

inserting a guiding catheter into a patient;

inserting a balloon angioplasty catheter through said guiding catheter;

inflating a distal balloon on said angioplasty catheter to perform angioplasty;

inflating a proximal balloon to seal between said guiding catheter and said angioplasty catheter, closing off an annular passage therebetween;

drawing blood from the patient through a channel in a sheath on the guiding catheter;

pumping the blood back into said annular passage up to said proximal balloon; and

directing the blood into the angioplasty catheter proximally of said proximal balloon to pump it into a lumen extending distally of said inflated second balloon, to the distal vascular anatomy.

23. The apparatus of claim 1, further comprising:

pump means in fluid communication with said annular passageway for pumping blood through said passage and said catheter, further comprising:

a pump body including a fluid inlet;

means on said body for elevating pressure of blood passing through said body; and

means in flow communication with said body for dampening pulsation of the blood as it emerges from said pump body, said pulsation-dampening means having a fluid outlet and further comprising:

a housing defining an accumulator cavity therein; and

a membrane covering said accumulator cavity, thereby isolating from said cavity blood passing to said outlet.

24. The apparatus of claim 9, further comprising:

pump means in fluid communication with said annular passageway for pumping blood through said passage and said catheter, further comprising:

a pump body including a fluid inlet;

means on said body for elevating pressure of blood passing through said body; and

means in flow communication with said body for dampening pulsation of the blood as it emerges from said pump body, said pulsation-dampening means having a fluid outlet and further comprising:

a housing defining an accumulator cavity therein; and

a membrane covering said accumulator cavity, thereby isolating from said cavity blood passing to said outlet.

25. The apparatus of claim 20, further comprising:

pump means in fluid communication with said annular passageway for pumping blood through said passage and said catheter, further comprising:

a pump body including a fluid inlet;

means on said body for elevating pressure of blood passing through said body; and

means in flow communication with said body for dampening pulsation of the blood as it emerges from said pump body, said pulsation-dampening means having a fluid outlet and further comprising:

a housing defining an accumulator cavity therein; and

a membrane covering said accumulator cavity, thereby isolating from said cavity blood passing to said outlet.

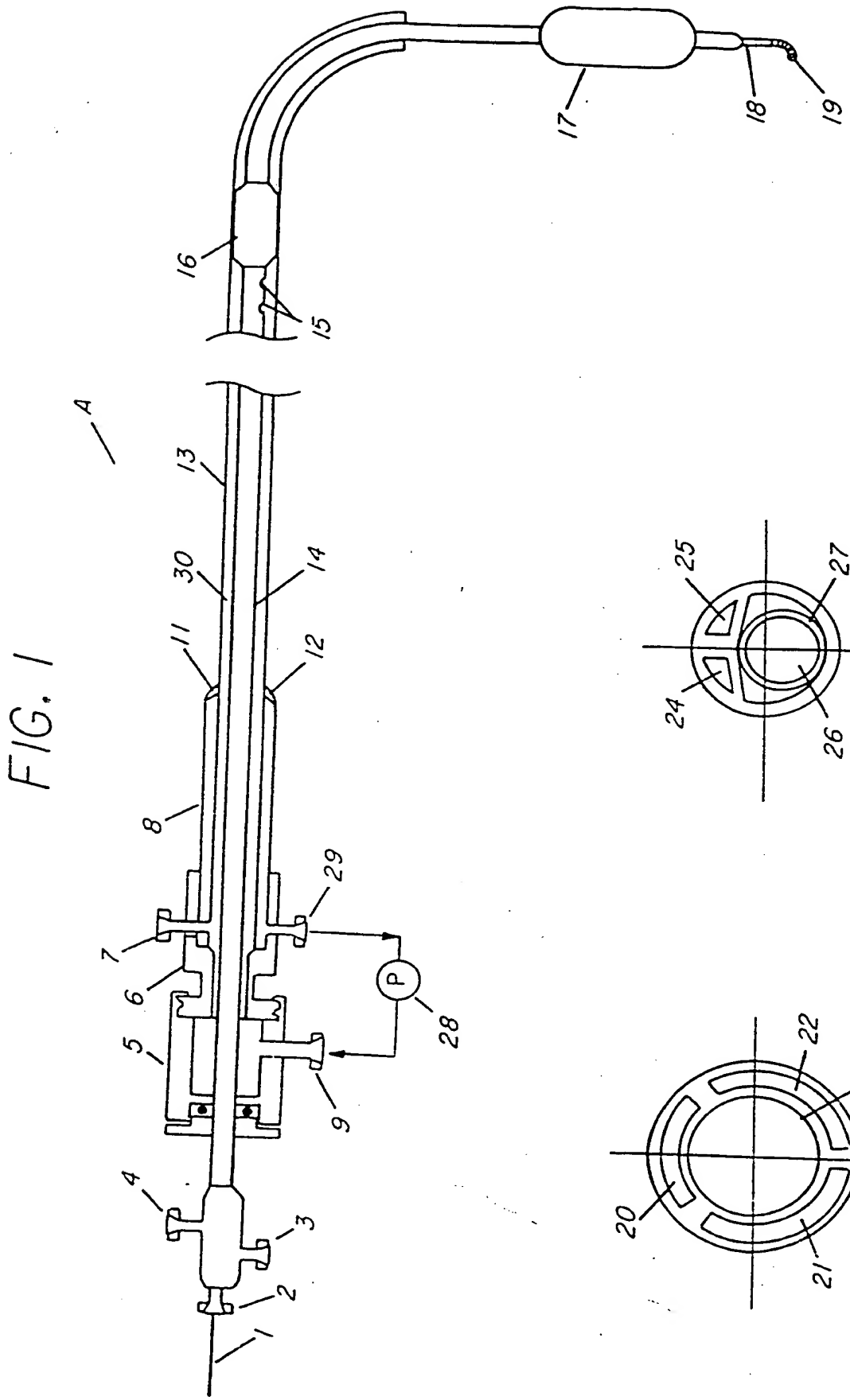


FIG. 1

FIG. 3

FIG. 2

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/03638

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5) A61M 29/00
US 604/96

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S.	604/53,96,101,102,164,167,246,264,30,35,39-43,132,151,152 606/194

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X Y	US, A, 4,771,777 (HORZEWSKI ET AL.) 20 SEPTEMBER 1988 See entire document.	1-3,11-19,22 20,23,25
Y	US, A, 3,572,979 (MORTON) 30 MARCH 1971 See entire document.	20,23,25
Y	US, A, 3,426,743 (CHESTNUT ET AL.) 11 FEBRUARY 1969 See entire document.	20,23,25

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
23 JULY 1991	19 AUG 1991
International Searching Authority	**Signature of Authorized Officer**
ISA/US	ANTHONY M. GUTOWSKI